

REMARKS

Claims 1-3, 5, 7, and 9-19 are active in the present application.

Applicants wish to thank Examiner Wong for the helpful and courteous discussion with their undersigned Representative on July 23, 2003. The content of this discussion is believed to accurately reflected and expanded upon in the amendments and remarks set forth herein. Applicants respectfully request favorable reconsideration in view of the amendments above and the comments below.

The rejection of Claims 1-3, 5, 7, and 9-19 under 35 U.S.C. § 103(a) in view of Muhammad et al is obviated in part by amendment and traversed in part.

On page 3 of the Office Action (paper number 29), the Examiner has indicated that she will once again not consider the Declaration that was filed on May 8, 2003. The first basis for this indication is that these data are “not commensurate in scope with the claims.” However, Applicants note that the basis for the Examiner’s conclusion is her apparent interpretation of Claim 1. It appears that the Examiner’s interpretation is that Claim 1 is not limited to “granules of a mixture” as Applicants have been arguing in the previous responses and have clearly demonstrated in the Declaration that was filed on May 8, 2003. In order to specifically indicate that the claims are, in fact, drawn to “granules of a mixture;” Applicants have amended the claims to define the inventive sweetener as “comprising granules of an admixture comprising Aspartame and Acesulfame-K as active ingredients” as suggested by the Examiner (see paper number 30).

Accordingly, the present claims relate to sweeteners which comprise *granules of an admixture* comprising Aspartame and Acesulfame-K as active ingredients, in which the

amount of Acesulfame-K is 5 to 90 % by weight based on the total amount of Aspartame and Acesulfame-K and wherein the maximum particle size of the granules is about 1,400  $\mu\text{m}$  or less and in which the granulated sweetener exhibits a rate of dissolution in water which is greater than that exhibited by granules of Aspartame alone (see Claim 1).

As previously presented, the inventors have surprisingly found that the presently claimed granulated sweeteners exhibit a higher dissolution rate as compared to either Aspartame alone or a mixture of Aspartame powder and Acesulfame-K powder.

The cited reference contains no disclosure or suggestion of such a granulated sweetener. Moreover, this reference contains no teaching which would suggest the improved solubility properties of the presently claimed granulated sweeteners. Accordingly, this reference cannot affect the patentability of the present claims.

Muhammad et al disclose certain sweetener compositions which contain Aspartame and Acesulfame-K. However, the sweetener compositions of Muhammad et al differ from those of the present claims in a number of key ways. As stated in the previous responses, the disclosure by Muhammad et al is deficient for the following reasons:

- 1) As conceded on page 2 of paper number 23, Muhammad et al is silent in regard to the particle size of the disclosed product. Not only is Muhammad et al silent with respect to the particle size, in the present specification, the Applicants have found that when the particle size of the granulated sweetener is 1,400  $\mu\text{m}$  or less the sweetener exhibits an *unexpectedly* improved dissolution rate (see, e.g., page 5, lines 4-10, of the specification);
- 2) The present claims are directed toward granulated sweeteners, while Muhammad et al is completely unconcerned with granulated sweeteners; and
- 3) The present claims are explicitly recite that the claimed sweeteners exhibit a dissolution rate which is greater than that exhibited by granules of Aspartame alone. In sharp contrast, Muhammad et al is concerned with the production of sweeteners which exhibit a delayed release (see, e.g., the Abstract of Muhammad et al).

Thus, the presently claimed sweetener compositions exhibit an improved rate of dissolution, which could not have been expected from the teachings of Muhammad et al.

To support the distinctions between the present invention and Muhammad et al and to underscore these deficiencies in the disclosure of Muhammad et al, Applicants filed a Declaration under 37 C.F.R. § 1.132 of Yuichi Suzuki, one of the named inventors of this application ("March 19<sup>th</sup> Declaration"), on March 19, 2002 demonstrating that the rate of dissolution of a series of mixtures of granules of Aspartame and granules of Acesulfame-K (analogous to Muhammad et al) were inferior to the dissolution rate of a series of granules of mixtures of Aspartame and Acesulfame-K (as in the present invention). Moreover, Applicants point to the data presented in Tables 1 and 2 given on pages 11 and 12 of the specification, which show that the presently claimed sweetener compositions exhibit an improved rate of dissolution.

To address the Examiner's direct concerns regarding the date of the March 19<sup>th</sup> Declaration, Applicants submitted a second Declaration under 37 C.F.R. § 1.132 of Yuichi Suzuki, one of the named inventors of this application ("March 26<sup>th</sup> Declaration"), on March 26, 2003 [executed copy filed on May 8, 2003]. In the March 26<sup>th</sup> Declaration, supplemental experiments with 90 % by weight ACE-K and 10 % by weight APM were presented to complete Table 2 of the March 19<sup>th</sup> Declaration. Table 2 from the March 26<sup>th</sup> Declaration is reproduced below for the Examiner's convenience:

Table 2: Time periods for dissolution (min)

Ratio of ACE-K present (% by weight)	5		20		50		90	
Particle size (μm)	Granules of mixture	Mixture of granules						
500 to 1,400	27*	33*	24	31	13*	25*	4**	26**
300 to 500	8*	17*	11	17	4*	13*	2**	13**
100 to 300	6*	16*	4	18	3*	15*	2**	14**
to 100	27*	32*	5	27	4*	22*	3**	14**
non-sieved	26	32	-	-	14	27	4	24

\*\* = Data presented in the March 26, 2003 Declaration under 37 C.F.R. §1.132

\* = Data presented in the March 19, 2002 Declaration under 37 C.F.R. §1.132

unmasked = Original Data presented in the specification in Table 2 appearing on page 12.

As is clearly evident from this data, as much as 90% ACE-K level unexpectedly shows that granules of mixture gave extremely shortened time periods for dissolution as compared with mixtures of granules, as was also shown at the other ratios provided in the March 19<sup>th</sup> Declaration.

As stated above, the claims have been amended to clearly indicate that the sweetener of the present invention, in fact, is drawn to "granules of an admixture comprising Aspartame and Acesulfame-K." Accordingly, the data are clearly commensurate in scope with the claims and clearly establishes the unexpected advantages flowing therefrom.

On page 3 of the present Office action (paper number 29), the Examiner has raised an additional point of concern that requires attention. The Examiner has stated, "Applicant does not provide statistical analysis of the data to support the conclusions." The Examiner further notes that Applicants state, "(e)ven assuming an [sic] over-accessed error as high as 10%, the conclusions drawn from the data are still clearly supported." Applicants note that this statement was never intended to suggest that the results differ from the prior art at a 90% confidence for the entire range. What Applications intended to establish by this statement is what one of remedial skill in the art would readily appreciate from inspection of the results set forth in Table 2 of the March 26<sup>th</sup> Declaration (see above): "that the rate of dissolution of a series of mixtures of granules of Aspartame and granules of Acesulfame-K (analogous to Muhammad et al) were inferior to the dissolution rate of a series of granules of mixtures of Aspartame and Acesulfame-K (as in the present invention)."

Again, Applicants draw the Examiner's attention to Table 2 above and note that in every ratio of Aspartame and Acesulfame-K, the dissolution rate of the inventive granules of a mixture is superior to that of mixtures of granules (i.e., Muhammad et al). Even at 5% Ace-K having a particle size of 100  $\mu\text{m}$  or less, the inventive sweetener has nearly a 16% improvement in dissolution rate as compared to mixtures of granules (i.e., Muhammad et al). The differences between the dissolution rates become even more significant at the remaining ratios of Aspartame and Acesulfame-K and particle sizes presented in Table 2. Once again, Applicants submit that such a result cannot be expected from the disclosure of Muhammad et al.

For all of these reasons, Applicants submit that Muhammad et al cannot support a *prima facie* case of obviousness and, even if it did Applicants have clearly rebutted this

finding due to presentation of unexpectedly superior properties flowing from the claimed invention. Accordingly, Applicants request withdrawal of this ground of rejection.

Applicants note that the amendments presented herein serve to clarify the invention to address the Examiner interpretation thereof. Applicants further note that all of the presently pending claims have been fully searched and examined on the merits. Therefore, Applicants submit that the Amendments presented herein cannot reasonably be considered to raise new issues for examination such as to necessitate not being entered. Accordingly, Applicants respectfully request that the amendments and remarks presented herein be entered and fully considered despite the "final" status of the current Office Action.

Applicants submit that the present application is in condition for allowance. Early notification to this effect is respectfully requested.

Respectfully submitted,

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AMENDMENTS TO THE CLAIMS

1. (Currently Amended) A ~~granulated~~ sweetener comprising granules of an admixture comprising Aspartame and Acesulfame-K as active ingredients, wherein the amount of the Acesulfame-K is 5 to 90% by weight based on the total amount of both components and wherein the maximum particle size of the granules is about 1,400  $\mu\text{m}$  or less and wherein said ~~granulated~~ sweetener exhibits a rate of dissolution in water which is greater than that exhibited by granules of Aspartame alone.

2. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, wherein said amount of the Acesulfame-K is 50 to 90% by weight.

3. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, wherein said amount of the Acesulfame-K is 20 to 90% by weight and wherein said maximum particle size of the granules is about 500  $\mu\text{m}$  or less.

4. (Canceled)

5. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, wherein said ~~granulated~~ sweetener exhibits a rate of dissolution in water which is greater than that exhibited by a mixture of Aspartame powder and Acesulfame-K powder, wherein said mixture of Aspartame powder and Acesulfame-K powder contains Aspartame and Acesulfame-K in the same relative amounts as said ~~granulated~~ sweetener.

6. (Canceled)

7. (Currently Amended) The ~~granulated~~ sweetener according to Claim 2, wherein said ~~granulated~~ sweetener exhibits a rate of dissolution in water which is greater than that exhibited by a mixture of Aspartame powder and Acesulfame-K powder, wherein said mixture of Aspartame powder and Acesulfame-K powder contains Aspartame and Acesulfame-K in the same relative amounts as said ~~granulated~~ sweetener.

8. (Canceled)

9. (Currently Amended) The ~~granulated~~ sweetener according to Claim 3, wherein said ~~granulated~~ sweetener exhibits a rate of dissolution in water which is greater than that exhibited by a mixture of Aspartame powder and Acesulfame-K powder, wherein said mixture of Aspartame powder and Acesulfame-K powder contains Aspartame and Acesulfame-K in the same relative amounts as said ~~granulated~~ sweetener.

10. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, wherein said ~~granulated~~ sweetener does not contain a binder.

11. (Currently Amended) The ~~granulated~~ sweetener according to Claim 2, wherein said ~~granulated~~ sweetener does not contain a binder.

12. (Currently Amended) The ~~granulated~~ sweetener according to Claim 3, wherein said ~~granulated~~ sweetener does not contain a binder.

13. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, wherein said ~~granulated~~ sweetener is prepared by:

(1) forming a mixture of Aspartame and Acesulfame-K; and

(2) granulating said mixture of Aspartame and Acesulfame-K by compacting granulation.

14. (Currently Amended) The ~~granulated~~ sweetener according to Claim 2, wherein said ~~granulated~~ sweetener is prepared by:

(1) forming a mixture of Aspartame and Acesulfame-K; and

(2) granulating said mixture of Aspartame and Acesulfame-K by compacting granulation.

15. (Currently Amended) The ~~granulated~~ sweetener according to Claim 3, wherein said ~~granulated~~ sweetener is prepared by:

(1) forming a mixture of Aspartame and Acesulfame-K; and  
(2) granulating said mixture of Aspartame and Acesulfame-K by compacting granulation.

16. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, which further comprises a diluent or excipient.

17. (Currently Amended) The ~~granulated~~ sweetener according to Claim 16, wherein said diluent or excipient is selected from the group consisting of sucrose, glucose, and mixtures thereof.

18. (Currently Amended) The ~~granulated~~ sweetener according to Claim 1, which further comprises ~~a~~ another another synthetic sweetener.

19. (Currently Amended) The ~~granulated~~ sweetener according to Claim 18, wherein said another synthetic sweetener is selected from the group consisting of Alitame, Saccharin, 3,3-dimethylbutylaspartylphenylalanine, and mixtures thereof.

SUPPORT FOR THE AMENDMENTS

Claims 1-3, 5, 7, and 9-19 have been amended.

Support for the amendment of Claims 1-3, 5, 7, and 9-19 can be found in the corresponding claims as previously filed and in the specification as originally filed.

No new matter has been added by the present amendment.